

NIHON KOHDEN
October 28, 1996

510(k) NOTIFICATION
OLG-1100A Pocket CO₂ MONITOR

SECTION 2 -510(k) SUMMARY

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Name and Address of Applicant
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The OLG-1100A PocketCap Pocket CO₂ Monitor is classified as Class II by the Division of Anesthesiology Devices and the Anesthesiology Device Classification Panel under 21 CFR Part 868.1400 "Analyzer, Gas, Carbon dioxide, Gaseous-phase" as per part 73 CCK.

Common names for the OLG-1100A PocketCap Pocket CO₂ Monitor include CO₂ Analyzer, CO₂ Monitor and CO₂ Indicator.

The predicate device is the Nellcor N-60 Stat-Cap Airway CO₂ Indicator per 510(k) #K915494, commercial distribution certification dated August 6, 1993.

The Nihon Kohden PocketCap Pocket CO₂ Monitor, model number OLG-1100A, is intended for medical purposes to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status. The device is intended as an indicator of patient carbon dioxide concentration during expiration and is not intended as the sole basis for medical diagnosis. The device will be available for use only by medical personnel within a hospital or other medical facility, at a remote site, or during transport from a remote site to a hospital or other medical facility. This device is not recommended for patients with low tidal volume such as patients younger than three (3) years of age or weighing less 22 pounds or patients with a respiration rate greater than or equal to 60 breaths per minute.

To date, no performance standards or special controls are known or established for this device as required by Section 514 of the Food, Drug and Cosmetic Act and implemented by 21 CFR Part 861.

The OLG-1100A PocketCap is not intended to be sterile.

The OLG-1100A PocketCap was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of acquiring, processing and displaying all functions of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the OLG-1100A PocketCap Pocket CO₂ Monitor is substantially equivalent to the Nellcor N-60 Stat-Cap Airway CO₂ Indicator.